

Nuclear Regulatory Commission

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that it will be transferred to persons exempt under § 30.14 of this chapter or equivalent regulations of an Agreement State, except in accordance with a license issued under § 32.11.

[72 FR 58487, Oct. 16, 2007]

§ 32.14 Certain items containing byproduct material; requirements for license to apply or initially transfer.

An application for a specific license to apply byproduct material to, or to incorporate byproduct material into, the products specified in § 30.15 of this chapter or to initially transfer for sale or distribution such products containing byproduct material for use pursuant to § 30.15 of this chapter will be approved if:

(a) The applicant satisfies the general requirements specified in § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding the product pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of byproduct material in each product;

(2) Details of construction and design of each product;

(3) The method of containment or binding of the byproduct material in the product;

(4) Procedures for and results of prototype testing to demonstrate that the material will not become detached from the product and that the byproduct material will not be released to the environment under the most severe conditions likely to be encountered in normal use of the product;

(5) Quality control procedures to be followed in the fabrication of production lots of the product and the quality control standards the product will be required to meet;

(6) The proposed method of labeling or marking each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container with the identification of the manufacturer or initial transferor of the product and the byproduct material in the product;

(7) For products for which limits on levels of radiation are specified in § 30.15 of this chapter, the radiation level and the method of measurement;

(8) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the product.

(c) Each product will contain no more than the quantity of byproduct material specified for that product in § 30.15 of this chapter. The levels of radiation from each product containing byproduct material will not exceed the limits specified for that product in § 30.15 of this chapter.

(d) The Commission determines that the byproduct material is properly contained in the product under the most severe conditions that are likely to be encountered in normal use and handling.

[31 FR 5316, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 43 FR 6922, Feb. 17, 1978; 63 FR 32971, June 17, 1998; 72 FR 58487, Oct. 16, 2007]

§ 32.15 Same: Quality assurance, prohibition of transfer, and labeling.

(a) Each person licensed under § 32.14 shall:

(1) Maintain quality assurance practices in the manufacture of the part or product, or the installation of the part into the product;

(2) Subject inspection lots to such testing as may be required as a condition of the license issued under § 32.14 taking a random sample of the size required by the tables in § 32.110, and for Lot Tolerance Percent Defective of 5.0 percent, accept or reject inspection lots in accordance with the directions of § 32.110; and

(3) Visually inspect each unit, except electron tubes containing byproduct material, in inspection lots. Any unit which has an observable physical defect that could affect containment of the byproduct material shall be considered as a defective unit.

(b) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (a)(2) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that the operating characteristic curve or confidence interval estimate for the

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alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(c) No person licensed under § 32.14 shall transfer to other persons for use under § 30.15 of this chapter or equivalent regulations of an Agreement State:

(1) Any part or product which has been tested and found defective under the criteria and procedures specified in the license issued under § 32.14, unless the defective units have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (b) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met such criteria as may be required as a condition of the license issued under § 32.14.

(d)(1) Label or mark each unit, except timepieces or hands or dials containing tritium or promethium-147, and its container so that the manufacturer or initial transferor of the product and the byproduct material in the product can be identified.

(2) For ionization chamber smoke detectors, label or mark each detector and its point-of-sale package so that:

(i) Each detector has a durable, legible, readily visible label or marking on the external surface of the detector containing:

(A) The following statement: "CONTAINS RADIOACTIVE MATERIAL";

(B) The name of the radionuclide ("americium-241" or "Am-241") and the quantity of activity; and

(C) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) of this chapter or equivalent regulations of an Agreement State.

(ii) The labeling or marking specified in paragraph (d)(2)(i) of this section is located where it will be readily visible when the detector is removed from its mounting.

(iii) The external surface of the point-of-sale package has a legible, readily visible label or marking containing:

(A) The name of the radionuclide and quantity of activity;

(B) An identification of the person licensed under § 32.14 to transfer the detector for use under § 30.15(a)(7) or equivalent regulations of an Agreement State; and

(C) The following or a substantially similar statement: "THIS DETECTOR CONTAINS RADIOACTIVE MATERIAL. THE PURCHASER IS EXEMPT FROM ANY REGULATORY REQUIREMENTS."

(iv) Each detector and point-of-sale package is provided with such other information as may be required by the Commission.

[31 FR 5317, Apr. 2, 1966, as amended at 34 FR 6652, Apr. 18, 1969; 39 FR 22129, June 20, 1974; 43 FR 6922, Feb. 17, 1978; 72 FR 58487, Oct. 16, 2007]

§ 32.16 Certain items containing byproduct material: Records and reports of transfer.

(a) Each person licensed under § 32.14 shall maintain records of all transfers of byproduct material and file a report with the Director of the Office of Federal and State Material and Environmental Management Programs by an appropriate method listed in § 30.6(a) of this chapter, including in the address: ATTN: Document Control Desk/Exempt Distribution.

(1) The report must clearly identify the specific licensee submitting the report and include the license number of the specific licensee.

(2) The report must indicate that the products are transferred for use under § 30.15 of this chapter, giving the specific paragraph designation, or equivalent regulations of an Agreement State.

(b) The report must include the following information on products transferred to other persons for use under § 30.15 or equivalent regulations of an Agreement State:

(1) A description or identification of the type of each product and the model number(s), if applicable;

(2) For each radionuclide in each type of product and each model number, if applicable, the total quantity of the radionuclide; and